



510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023893

Submitter:

Tosoh Medics, Inc.
347 Oyster Point Blvd., Suite 201
South San Francisco, CA 94080
Phone: (650) 615-4970
Fax: (650) 615-0415

Contact Person:

Lois Nakayama
Manager, Quality Assurance

Date of Summary Preparation:

November 8, 2002

Device Name:

ST AIA-PACK CEA

Classification Name:

System, Test, Carcinoembryonic Antigen

Predicate Device:

Tosoh AIA-PACK CEA
Tosoh Corporation
Tokyo, Japan
P910053

Device Description:

The ST AIA-PACK CEA is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK. CEA present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the AIA-PACK. The magnetic beads are washed to remove unbound enzyme-labeled monoclonal antibody and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the CEA concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Statement of Intended Use:

ST AIA-PACK CEA is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Carcinoembryonic Antigen (CEA) in human serum to aid in the management of cancer patients in whom changing concentrations of CEA are observed on specific TOSOH AIA System analyzers.

Substantial Equivalence:

This Special 510(k) is for a modification in the packaging, incubation period, conjugate concentration and certain components of the conjugate diluent of the AIA-PACK CEA, which was previously cleared as P910006 on February 19, 1993. The intended use, assay principles, antibody type, analyte detected, and performance characteristics of both assays are equivalent.

Conclusion:

The modified ST AIA-PACK CEA, as described in this Special 510(k) is substantially equivalent to the predicate device. The proposed modifications in packaging, incubation period, conjugate and conjugate diluent are not substantial changes and do not affect the safety and effectiveness of the device.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 18 2002

Ms. Lois Nakayama
Manager, Quality Assurance
Tosoh Medics, Inc.
347 Oyster Point Blvd. – Suite 201
South San Francisco, CA 94080

Re: k023893

Trade/Device Name: ST AIA-PACK CEA Enzyme Immunoassay
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: DHX; JIS
Dated: November 20, 2002
Received: November 22, 2002

Dear Ms. Nakayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

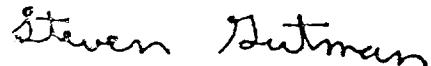
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 -

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure



TOSOH

TOSOH MEDICS, INC.

Indications for Use Statement

Device Name ST AIA-PACK CEA Enzyme Immunoassay

Indications for Use ST AIA-PACK CEA is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Carcinoembryonic Antigen (CEA) in human serum to aid in the management of cancer patients in whom changing concentrations of CEA are observed on specific TOSOH AIA System Analyzers.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. P. Lewis for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023893

Prescription Use
(Per 21CFR 801.109)

OR

Over-The-Counter Use